RECORD AND BRIEFS

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IN THE

Supreme Court of the United States

SANDOZ, INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE BIOSIMILARS COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the Biosimilars Council, a division of the Generic Pharmaceutical Association, files this brief to urge this Court to grant the petition for a writ of certiorari filed by Sandoz, Inc.

The Biosimilars Council's members include companies and stakeholder organizations working to develop biosimilar products for the United States pharmaceutical market. Biosimilars are highly similar or interchangeable versions of Food and Drug Administration ("FDA")-licensed branded biologic medicines. A branded biologic in this context is known as a "reference product" and its licenseholder as the "Reference Product Sponsor" or "RPS." Congress established an expedited FDA approval pathway for biosimilars in 2010 in the Biologics Price Competition and Innovation Act ("BPCIA"), as part of the Affordable Care Act.[2]

This case raises critical issues concerning the proper interpretation of the BPCIA's procedures for

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[1] *Amicus* gave notice of its intention to file this brief on March 4, 2016, and all parties have consented to the brief's filing. No counsel for a party authored this brief, in whole or in part; no counsel for a party made a monetary contribution intended to fund the preparation of submission of this brief; and no one other than *amicus*, its members, or its counsel made such a monetary contribution. Funding for the Biosimilars Council includes regular contributions from its members, including Petitioner.

[2] Reference products are licensed under section 351(a) of the Public Health Services Act ("PHSA"), 42 U.S.C. § 262(a). The expedited biosimilars pathway was added by the BPCIA to the PHSA as section 351(k), 42 U.S.C. § 262(k).

the resolution of patent disputes between a biosimilar applicant and an RPS – specifically, whether Congress intended the "notice of commercial marketing" provisions that are part of these procedures to (1) delay commercial marketing of biosimilars for an additional six months beyond the statute's express 12-year exclusivity period for reference products or (2) confer on an RPS a private right of action to compel notice through an automatic injunction. The Federal Circuit answered these questions "yes," but the correct answers are "no."

Amicus and its members have a strong, industry-wide interest in ensuring that the BPCIA, including the notice provisions, are interpreted consistent with Congress' overriding goal of expediting patients' access to affordable versions of badly needed medicines. The Federal Circuit's erroneous decision, if left uncorrected, would undermine these goals by (1) denying patients access to biosimilars for six months longer than Congress intended and (2) enabling an RPS to effect this delay through an automatic injunction, outside the remedial framework Congress established as part of the BPCIA's patent dispute resolution process.

The Federal Circuit's decision will apply to other biosimilars, not just the Sandoz product at issue in this case, shaping the overall biosimilars landscape just as the BPCIA and the biosimilars industry are coming of age. One district court has already relied on the Federal Circuit's decision to enjoin the marketing

of another biosimilar,[3] similar injunctions have been sought in two other cases,[4] and the notice issue will inevitably resurface in cases involving new biosimilar applications filed with FDA. The industry-wide and nation-wide impact of the Federal Circuit's error, and therefore *amicus*' interest in this Court's plenary review of that decision, is apparent.

STATEMENT

A. The Promise of Biosimilars

Biologics are large-molecule medicines derived from living organisms. They are among the most expensive drug products in the United States and account for an increasing share of U.S. prescription drug costs. Federal Trade Comm'n, Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposal on Competition, 78 Fed. Reg. 68,840 (Nov. 15, 2013) (noting that biologics are "among the most important pharmaceutical products in the United States" and "comprise the fastest growing sector within pharmaceuticals."). In 2010, spending on biologics in the United States was $67 billion, or approximately 20 percent of overall drug spending. IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of*

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[3] *Amgen Inc. v. Apotex Inc.*, No. 15-61631, slip op. at 2-8 (S.D. Fla. Dec. 9, 2015), appeal docketed, No. 16-1308 (Fed. Cir. Dec. 11, 2015).

[4] *Janssen Biotech, Inc. v. Celltrion Health Care Co.*, No. 15-10698 (D. Mass. Aug. 24, 2015), ECF No. 72; *Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Nov. 6, 2015), ECF No. 11.

2010 4, 6 (Apr. 2011).[5] By 2013, spending on biologics in the United States had increased nearly 40 percent to $92 billion, or approximately 28 percent (also a 40 percent increase) of overall drug spending. Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry*, Matrix Global Advisors 4 (Feb. 2015).[6]

On average, biologics cost $45 per day, compared to $2 per day for small-molecule drugs. Steve Pociask, *Lifesaving Drugs at Lower Costs*, American Consumer Institute Center for Citizen Research ConsumerGram 2 (July 22, 2014).[7] Certain biologics cost tens or even hundreds of thousands of dollars per patient per year. For example, Humira®, which treats arthritis and other conditions, costs $50,000/year, and Cerezyme®, which treats Gaucher's Disease, costs $200,000/year. Erwin A. Blackstone and Joseph P. Fuhr, *Innovation and Competition: Will Biosimilars Succeed?* Biotechnology Healthcare, 24-27 (Spring 2012).[8]

The BPCIA's expedited approval pathway allows FDA to approve a biosimilar based on the agency's previous approval of a reference product, thereby both (1) reducing biosimilars' development

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[5]https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202010/Use_of_Meds_in_the_U.S._Review_of_2010.pdf.

[6]http://www.matrixglobaladvisors.com/storage/MGA_biosimilars_2015_web.pdf.

[7]http://www.theamericanconsumer.org/2014/07/new-consumergram-lifesaving-drugs-at-lower-costs/.

[8]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351893/.

costs (and therefore their prices) and (2) expediting FDA review, market competition, and patient access to affordable medicines. Increased competition from biosimilars holds the potential for enormous savings for the U.S. healthcare system, with one study estimating savings at more than $44 billion over 10 years. Andrew Mulcahy, Zach Pretmore & Soren Mattke, *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Health Advisory Servs. (2014).[9]

B. The BPCIA's Compromise Between Competition and Innovation: 12-Year Exclusivity in Exchange for the Expedited Approval Pathway

The BPCIA represents Congress' carefully-calibrated effort to increase competition in pharmaceutical markets while also preserving incentives to innovate. App. 4a, 87a. To achieve the goal of increased competition, Congress established the expedited biosimilar approval pathway. To achieve the goal of encouraging innovation, and as a *quid pro quo* for the new approval pathway, Congress granted RPS's 12 years of additional statutory exclusivity. 42 U.S.C. § 262(k)(7)(A) (providing that FDA shall not "ma[k]e effective [its licensing of a biosimilar] until the date that is 12 years after the date on which the reference product was first licensed" by FDA). *See also* Thomas M. Burton, *Biosimilar Drugs Face U.S. Test: FDA Panel Will*

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[9] http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

Decide Whether to Recommend Approval, Wall St. J., Jan. 6, 2015, at 2 ("The 2010 Affordable Care Act created an abbreviated pathway for biosimilars to enter the U.S. market . . . . *As a tradeoff for the industry, the law gave biologic drugs a 12-year period of exclusivity that protected them from competition from a biosimilar.*") (emphasis added).[10]

The length of the exclusivity was a particularly hard-fought piece of the overall innovation/competition compromise struck by Congress. The Federal Trade Commission argued that no exclusivity was needed to encourage innovation given patent protections and market pricing incentives, while the Obama Administration supported an exclusivity period of only seven years. Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 787-91 (Nov. 4, 2010). In the end, the 12-year exclusivity was "vetted exhaustively" and was the product of "a genuinely bipartisan Member-level compromise" that was "reached in the summer of 2007 [and] remained intact through three subsequent years of legislative debate" until it "found its place in the final law." *Id.* at 816-17.

C. The BPCIA's "Patent Dance"

As part of Congress' efforts to balance the goals of competition and innovation, the BPCIA contains an extensive, integrated framework, contained in

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[10] http://www.wsj.com/articles/biosimilar-drugs-face-u-s-test-1420590926.

subsection 351(l) (42 U.S.C. § 262(l)), for the resolution of patent disputes between a biosimilar applicant and an RPS.

As a first step in this process, the biosimilar applicant may provide the RPS with its application within 20 days of submission to FDA. 42 U.S.C. § 262(l)(2)(A). If the applicant shares its application, there follows a multi-stage information exchange process – which has come to be known as "the patent dance" – through which the parties can identify patents to be litigated in connection with the proposed biosimilar. This process begins with the parties' exchange of initial patent lists (42 U.S.C. § 262(l)(3)) and can end with a final list that is generated either by agreement of the parties or by following additional steps set forth in subsection 351(l). 42 U.S.C. § 262(l)(4)-(l)(6).

D. The Role of the Notice Provisions in the "Patent Dance"

The notice provisions at issue appear in BPCIA subsection 351(l)(8) (42 U.S.C. § 262(l)(8)) and, as explained in Judge Chen's dissent from the Federal Circuit's decision, are "part and parcel of the integrated litigation management process contemplated in" subsection 351(l). App. 43a. The undisputed purpose of the notice provisions is to trigger the right to litigate immediately, *inter alia*, patents that are included on the preliminary lists exchanged during the "patent dance," but not on the parties' final list. App. 7a (explaining that the notice provisions "allow[] the RPS a period of time to seek a preliminary injunction based on patents that the

parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents (collectively, 'non-listed patents')").[11]

Under 42 U.S.C. § 262(l)(8)(A), a biosimilar applicant provides "notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." And under 42 U.S.C. § 262(l)(8)(B), after receiving notice, the RPS:

> may seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of the [biosimilar] until the court decides the issue of patent validity, enforcement and infringement with respect to any patent that is –
>
> (i) included in the list provided by the [RPS] under [42 U.S.C. § 262(l)(3)(A)] or in

[11] This two-step litigation process was a compromise intended to allow the biosimilar applicant and the RPS to defer litigation of some patent rights while preserving for the RPS the opportunity to enforce those patents (or newly issued patents) at a later date. Deferral would also potentially benefit a RPS by avoiding a challenge to some of its patent rights at a time when it may be uncertain whether a biosimilar application would be approved, thereby preserving the exclusivity benefit of such patent rights with respect to other potential infringing products (novel or biosimilar).

> the list provided by the [biosimilar] applicant under [42 U.S.C. § 262(l)(3)(B)]; and
>
> (ii) not included, as applicable, on –
>
> (I) the list of patents described in [42 U.S.C. § 262(l)(4)]; or
>
> (II) the lists of patents described in [42 U.S.C. § 262(l)(5)(B)].

In other words, notice provides a safety net that gives the RPS at least 180 days of advance warning of the commercial launch of a biosimilar, so that the RPS can *try* to enjoin the launch on the basis of any patent not already scheduled for resolution as a result of the full "patent dance."

E. The BPCIA'S Express Consequences of Not Providing Notice

The BPCIA's subsection 351(l) integrated patent dispute resolution framework also clearly sets forth the consequences for failure to provide information during each stage of the "patent dance" – including, of particular importance here, the failure to provide notice under subsection 351(l)(8)(A). If, as Petitioner Sandoz did in this case, the biosimilar

applicant declines to take the initial step of providing its application to the RPS, the RPS may initiate patent litigation with respect to *any* patent it deems relevant. 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii) (adopted as part of the BPCIA as an amendment to the Patent Act). And if the biosimilar applicant fails to complete any of the subsequent steps of the "patent dance" – *including* the step of providing notice – the RPS may initiate patent litigation on any patent contained on the preliminary patent list provided by the RPS under subsection 351(l)(3)(A). 42 U.S.C. § 262(l)(9)(B) (setting forth patent litigation remedy for a biosimilar applicant's "fail[ure] to complete an action required of the . . . applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), *or paragraph (8)(A)* [*i.e.*, the notice provisions]."") (emphasis added)).

F. The Federal Circuit's Decision and Judge Chen's Dissent

In this case, Petitioner Sandoz provided the RPS, Amgen, with notice related to the commercial marketing of Sandoz's biosimilar version of Amgen's product Neupogen® before FDA licensed Sandoz' product (which is known as Zarxio®). Sandoz did not share its application with Amgen pursuant to BPCIA subsection 351(l)(2)(A), thereby permitting Amgen, as it in fact did, to initiate patent litigation with respect to any patent it deemed relevant. 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

As part of its case against Sandoz, Amgen claimed that notice under the BPCIA had to follow FDA licensure and that Amgen could compel such

post-licensure notice through an automatic injunction. Reversing the district court (App. 73a-76a), the Federal Circuit agreed. App. 18a-26a.[12]

First, the Federal Circuit held that under the plain language of the BPCIA, notice could only be given after FDA licensure of the biosimilar. The Federal Circuit relied on the statute's reference to notice regarding "the product *licensed* under subsection (k)" (App. 19a) (emphasis added), reasoning that because the statute refers to notice of intent to market a biosimilar that has already been "licensed" by FDA, notice itself can only be given after the product is "licensed." App. 19a-23a. The court of appeals added that requiring notice to follow FDA licensure would "ensure[ ] the existence of a fully crystallized controversy regarding the need for injunctive relief." App. 21a.

Second, the Federal Circuit held that post-licensure notice under subsection 351(l)(8)(A) was mandatory and that an RPS like Amgen could compel such notice through a private action for an automatic injunction. App. 23a-26a. The Federal Circuit disagreed that an automatic private injunction conflicted with Congress' chosen remedial scheme for lack of notice under BPCIA subsection 351(l)(9)(C), holding that the notice provisions operated as a "standalone" requirement in cases where, as here, the

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[12] On a separate issue that is not the subject of Sandoz's petition, the Federal Circuit (Judge Lourie, joined by Judge Chen) properly held that the application-sharing provisions in BPCIA subsection 351(l)(2)(A) were not mandatory and that Amgen was therefore not entitled to an automatic injunction forcing Sandoz to provide Amgen with its application for Zarxio®. App. 12a-18a.

biosimilar applicant had not provided its application to the RPS and therefore had failed to trigger the BPCIA "patent dance." App. 25a. The Federal Circuit held that Sandoz could not have given operative notice until March 6, 2015, the date FDA licensed Zarxio®, and was enjoined from marketing its product until 180 days later, on September 2, 2015.

Judge Chen dissented from the majority's conclusion that Amgen could compel notice through an automatic injunction. App. 42a-55a. He explained that notice was not a standalone requirement, but rather "part and parcel of the integrated litigation management process contemplated in [BPCIA subsections 351(l)(2)-(l)(7)]." App. 43a. He further explained that the BPCIA contained an express remedy for lack of notice in subsection 351(l)(9)(B), which allowed an RPS that did not receive notice to initiate immediate patent litigation – not to obtain an "automatic 180-day injunction." App. 52a. Judge Chen added that the practical effect of treating notice as a post-licensure requirement enforceable through an automatic private injunction was to provide the RPS with "an atextual 180-day exclusivity windfall" on top of the BPCIA's express 12-year exclusivity period. App. 53a. *See also* App. 43a ("I do not view (l)(8)(A) as a 'standalone provision' that provides, implicitly, the RPS a 180-day injunction beyond the express twelve-year statutory exclusivity period.")

SUMMARY OF ARGUMENT

The Federal Circuit's decision conflicts with the text, structure and purpose of the BPCIA in three critical respects. First, it blocks patients' access to

affordable medicines for six months longer than Congress intended. Second, it delays resolution of patent disputes between an RPS and a biosimilar applicant until after FDA licensure of the biosimilar. Third, permitting an RPS to compel notice through an automatic private injunction conflicts with Congress' express remedy for lack of notice, as well as with the traditional equitable test for permanent injunctions, from which Congress showed no intention of departing in the BPCIA notice section.

The Federal Circuit's decision, if left uncorrected, would critically undermine Congress' overarching goal of providing patients with swift access to affordable, essential medicines. This Court's review is especially critical at this moment in time, when the biosimilars industry is coming of age and looking to the courts for definitive interpretations of key provisions of the BPCIA that are consistent with, and will advance, the statute's overarching purposes.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Decision Adds an Extra-Textual 180-Day Windfall to the BPCIA's Express 12-Year Exclusivity, in Conflict with the Statute's Text and Overarching Purposes.

The Federal Circuit's holding that 180-day notice of commercial marketing of a biosimilar is mandatory and can only be effective after FDA licensure of the biosimilar would, as noted by the District Court and Judge Chen's dissent, effectively grant an RPS six additional months of statutory

exclusivity, beyond the 12-year exclusivity period expressly included in the BPCIA. Under the plain terms of the BPCIA and FDA's reading of the statute, FDA cannot finally license a biosimilar until expiration of the exclusivity. 42 U.S.C. § 262(k)(7)(A). *See also* Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biologics Products Filed Under Section 351(c) of the PHS Act* 2 (Aug. 2014) (describing the 12-year exclusivity as "the period of time in which . . . FDA is not permitted to license a [biosimilars application] that references a reference product.")[13] And if the applicant must provide notice but cannot do so until after licensure, as the Federal Circuit held, the 180-day notice period will always add to the 12-year exclusivity.[14] This reading of the BPCIA directly conflicts with both the statute's plain text and with Congress' overall goal of expediting patients' access to needed medicines.

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[13] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm407844.pdf.

[14] The Federal Circuit suggested that its reading of the notice provisions "does not necessarily conflict with" 12-year exclusivity where (unlike in Sandoz's case) the exclusivity runs concurrent with FDA review of the biosimilar application. App. 22a (noting that the "extra 180 days [of exclusivity] will not likely be the usual case, as [biosimilars applications] will often be filed during the 12-year exclusivity period"). But under the majority's reading of the notice provisions, notice *must* follow FDA licensure. And because licensure *must* in turn follow expiration of the exclusivity, the majority's holding means that notice perforce *must* follow expiration of the 12-year exclusivity and operates to extend that period, regardless of when exclusivity runs.

The Statutory Text

As Petitioner explains (Pet. 23-26), and as the District Court held (App. 73a-76a), the plain text of the notice provisions in no way circumscribes the timing of notice. The Federal Circuit's interpretation of the statute relies exclusively on a flawed reading of the word "licensed" in 42 U.S.C. § 262(l)(8)(A) (which refers to "notice to the [RPS] not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)" (emphasis added)). The Federal Circuit reasoned that because the statute referred to a biosimilar that had been "licensed" by FDA, the notice itself – not just the product's marketing – had to occur after the biosimilar had been "licensed." App. 20a. But the word "licensed" is clearly intended to modify "the product" that will be commercially marketed, not to limit *the timing* of notice. Congress used the past-tense "licensed" because the right to commercially market a product, regardless of when notice is given, *can only exist after FDA licensure*. In other words, the statute simply provides for notice that the applicant intends to market a biosimilar *once the product has been licensed*, not to set the earliest date notice can be provided. This is the reading adopted by the district court in this case (App. 73a-76a), and it is correct.

This straightforward reading also addresses the Federal Circuit's concern (App. 20a) that Congress did not instead refer in the notice provision to "the biological product that is the subject of the application" under subsection (k). As the District Court explained, a biosimilar that is merely the

"subject of [an] application" *cannot be* commercially marketed, and "[i]t would be nonsensical for [the notice provisions] to refer to a biosimilar as the subject of a subsection (k) application because upon its 'first commercial marketing' a biosimilar must, *in all instances*, be a 'licensed' product." App. 75a (emphasis added).

As the Petition notes (Pet. 23, 25), Congress could have clearly circumscribed the timing of notice by referring to notice "after" FDA licensure or referring to the applicant as the "holder" of an approved application or license. It did not use either of these straightforward formulations, and the language it did use provides no support for the post-licensing condition adopted by the Federal Circuit.

The Overarching Goals of the BPCIA

Even if the statutory text were ambiguous (which it is not), it is inconceivable that Congress intended to disrupt the BPCIA's carefully-crafted exclusivity compromise – and to further delay patients' access to affordable medicines – by adding *sub silentio* six additional months to the express 12-year exclusivity period.

As discussed *supra* p. 6, 12-year exclusivity was a critical, heavily-negotiated piece of the BPCIA's grand compromise between competition and innovation. Congress could not possibly have intended to alter such a key element of this compromise through the indirect means of the BPCIA's notice provisions. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not

alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes.") (citations omitted); App. 76a ("Had Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so.") Indeed, when Congress did choose to extend exclusivity beyond 12 years, as it did when the RPS conducts pediatric studies on the reference product, it did so simply and directly. 42 U.S.C. § 262(m)(2)(A) (where pediatric studies are conducted, the 12-year exclusivity "[is] deemed to be 12 years and 6 months rather than 12 years.")

Of course, by its very definition and as Congress intended (subject to the express "pediatric extension"), the statutory 12-year exclusivity period is intended to prevent a biosimilar's launch for 12 years *and no more*. Yet the Federal Circuit's reading of the statute would frustrate this basic congressional policy choice by making the end of the exclusivity period an essentially meaningless event and the end of the notice period 180 days later the true relevant trigger for marketing. A reading of the BPCIA under which notice may be given pre-FDA licensure, so that it does not operate to extend the BPCIA's express 12-year exclusivity period, is the only reading that is consistent with "the whole [BPCIA] and . . . its object and policy." *United States Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (citation omitted). *See also Kokoszka v. Belford*, 417 U.S. 642, 650 (1974) ("When interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute (or statutes on

the same subject) and the objects and policy of the law, as indicated by its various provisions, and give to it such a construction as will carry into execution the will of the Legislature.") (citation omitted)).

II. The Federal Circuit's Interpretation Also Conflicts with the BPCIA's Goals by Postponing Patent Disputes Until After FDA Licensure of the Biosimilar.

Congress created the BPCIA's integrated patent dispute resolution framework to expedite the resolution of patent disputes – preferably *before* FDA is ready to approve the biosimilar application – as part of its overall goal of making affordable versions of critically important medicines available to patients as soon as possible. App. 45a (noting that BPCIA subsection 351(l) is designed to "lead[] up to the expected patent infringement suit that comes *during the pendency of* a [biosimilars] application" (emphasis added)). Even the trade association for the brand biologics industry, the Biotechnology Industry Association ("BIO"), has acknowledged that the BPCIA is designed "to identify and resolve patent issues *before a biosimilar is approved.*" *Biologics & Biosimilars: Balancing Incentives for Innovation*, Hr'g of Subcomm. on Courts and Competition Policy of H. Jud. Comm., 111th Cong. 77 (2009) (emphasis added).

The notice provisions, aptly described by Judge Chen as "part and parcel" of this framework (App. 43a), serve this goal directly by allowing an RPS to initiate immediate litigation on certain patents that are not part of the final "patent dance" list. 42 U.S.C. § 262(l)(8)(B); App. 7a. But the Federal Circuit's

reading of the notice provisions has the countervailing effect, by postponing notice – and therefore even the initiation, much less resolution, of litigation regarding "unlisted patents" – until *after* FDA approval. Congress cannot have intended this result, which is so plainly contrary to the statute's overall goals and to the patent dispute resolution framework of which the notice provisions are "part and parcel." App. 43a.

Further, as the Petition notes (Pet. 26), notice for the purpose of alerting an RPS to the future marketing of a biosimilar is superfluous in a post-licensure context. FDA licensure is itself a public event that obviates the need for any further notification to the RPS of the biosimilar applicant's plans to go to market. Put another way, the notice provisions should be not be read to achieve an objective to which they are completely unnecessary. *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (noting canon of statutory interpretation that statutes should be read to avoid making any provision "superfluous, void, or insignificant" (citation omitted)).

The Federal Circuit justified its reading of a post-licensing requirement into the notice provisions on the grounds that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." App. 21a. But this explanation misses the point that the entire subsection 351(l) framework – including the notice provisions – is premised on resolution of patent disputes before, and is in no way predicated on, FDA licensure. App. 46a ("Importantly, subsection (l) does not relate to the FDA approval process (for that see

subsection (k)."). No other provision of subsection 351(l) is triggered by FDA licensure, and the notice provisions should not be read differently, outside the context of the statute's overarching goals generally or the patent dispute resolution framework in particular.

III. The Federal Circuit's Extra-Statutory Injunctive Remedy Conflicts with Congress' Chosen Remedial Scheme in the BPCIA and with Traditional Equitable Standards for Injunctions.

"[P]rivate rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001) (citation omitted). And where "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Empls.*, 489 U.S. 527, 533 (1989) (citation omitted). *See also Alexander*, 532 U.S. at 290 ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others.")

The Federal Circuit's decision runs afoul of these basic tenets. As part of the BPCIA's integrated patent dispute resolution framework, Congress specified that if a biosimilars applicant fails to provide notice under subsection 351(l)(8)(A), the RPS may immediately initiate litigation on any patent on the RPS' original list. 42 U.S.C. § 262(l)(9)(B). This remedy, like the others in BPCIA subsections 351(l)(9)(B) and (C), is patent litigation-based, allowing the RPS to bring patent infringement actions more quickly than would otherwise be possible – all in the service of the statute's overall goal of expediting

access to affordable medicines. In short, Congress expressly chose a procedural mechanism to remedy the failure to provide notice, rather than creating an enforceable substantive right to notice itself.

The Federal Circuit acknowledged the existence of the subsection 351(l)(9)(B) remedy for failure to provide notice, but held that this remedy "does not apply" where, as here, the biosimilars applicant failed to provide its application to the RPS pursuant to BPCIA subsection 351(l)(2)(A). App. 25a. The problem with this analysis is that it does not excuse the Federal Circuit's selection of a remedy that it totally outside of, and inconsistent with, the BPCIA subsection 351(l) framework. It is true that in cases where the biosimilars applicant fails to provide its application, the subsection 351(l)(9)*(B)* remedy is unnecessary because BPCIA subsection 351(l)(9)*(C)* permits an RPS to bring immediate litigation on *any* patent. However, both in cases where the applicant does not even start the "patent dance" because it declines to provide its application *and* in cases where the applicant begins the dance but does not provide notice, Congress provided a patent-litigation based remedy under the BPCIA. In neither case did Congress contemplate the *completely different* remedy – entirely untethered from the BPCIA subsection 351(l) framework – of a private injunction compelling notice. And the courts lack authority to add such a remedy themselves.

The Federal Circuit compounded its error by making available an *automatic* private injunction to compel notice, without regard for the traditional factors governing awards of permanent injunctions.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (identifying factors as (1) irreparable injury, (2) inadequate remedies at law, (3) balance of hardships favors an injunction, and (4) public interest favors an injunction). This extra-statutory leap violated this Court's admonition that "a major departure from the long tradition of equity practice," in the form of an automatic injunction, "should not lightly be implied." *Id.* at 395 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982)). Nothing in the BPCIA suggests that Congress intended such a departure in connection with BPCIA notice.

Indeed, the opposite is true. As Judge Chen noted (App. 52a-53a), Congress knows exactly how to use automatic injunctions to delay the marketing of drug products when it wants. In the 1984 Hatch-Waxman law governing small molecule generic drugs, Congress enacted a 30-month automatic stay of FDA's approval of a generic drug application that was the subject of patent litigation, providing that approval "shall be made effective upon the expiration of" the 30-month period. 21 U.S.C. § 355(j)(5)(B)(iii). Congress could similarly have provided in the BPCIA that FDA licensure of a biosimilar "shall be made effective upon the expiration of" the notice period, but it did not do so, signaling its intent not to create an automatic injunction. *Cent. Bank of Denver N.A. v. First Interstate Bank of Denver N.A.*, 511 U.S. 164, 176 (1994) (Congress did not impose aiding and abetting liability under the Securities Exchange Act and its use of "aid" and "abet" in other statutes showed that "Congress knew how to impose aiding and abetting liability when it chose to do so.") (citations omitted)).

Moreover, Congress employed an automatic injunctive remedy *elsewhere* in BPCIA subsection 351(l). 42 U.S.C. § 262(l)(1)(H) (providing for automatic injunction in connection with unwarranted disclosure of confidential information). Congress' express provision for an automatic injunction in a separate part of subsection 351(l) indicates that it did not intend to provide the same remedy in that section in connection with notice. *Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (citation omitted).[15]

This Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination" of a statutory violation. *eBay*, 547 U.S. at 392-93 (citations omitted). It should do so again here.

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[15] Amgen could have sought (and could still seek) a preliminary injunction under the normal multi-factor test as part of its patent infringement action against Sandoz under the BPCIA, *see* 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), but has never done so, trying instead to end-run that process by claiming the right to an automatic injunction under the notice provisions.

IV. This Court's Review and Correction of the Federal Circuit's Erroneous Decision Is Critical to the Continued Growth of the Biosimilars Industry and to the Realization of the BPCIA's Objectives.

The BPCIA stands at a crossroads. Congress created the statute's expedited approval pathway in 2010 with the goal of providing safe, effective alternatives to expensive biologic medicines and thereby helping dramatically cut spiraling health care costs. In just a few years, taking Congress' lead, the biosimilars industry has grown and continues to grow by leaps and bounds (as evidenced by the very existence of the Biosimilars Council). More biosimilars are under development, applications for FDA approval of biosimilars have increased, and agency activity in this area is accelerating. Even Amgen itself has filed a biosimilars application, for a version of the arthritis drug Humira®.

At this early stage of the BPCIA's existence, biosimilars companies, patients, health insurers (both private and government), and other stakeholders are looking to the courts to interpret the statute correctly and conclusively, so that FDA and industry can operate in a settled business environment and Congress' vision of billions of dollars of cost savings for the U.S. healthcare system has the chance of being realized. The Federal Circuit's erroneous interpretation of the BPCIA threatens to broadly undermine Congress' vision and to dramatically reduce anticipated savings to the U.S. healthcare system from biosimilars, just as the industry is coming of age.

This case provides one example of the effect of the Federal Circuit's interpretation: patients were denied access to Petitioner's biosimilar product Zarxio®, an affordable alternative to Amgen's product Neupogen®, until September 3, 2015, even though FDA had approved Petitioner's application six months earlier. But although Zarxio® is now on the market, the Federal Circuit's misreading of the notice provisions will delay patients' access to other biosimilars. Indeed, as noted above, several district courts have followed the Federal Circuit's decision on the notice issue or are currently considering that issue in connection with drugs other than Zarxio®. This Court must step in and provide definitive, correct guidance on this critical issue to the lower courts, to industry, to FDA, and to patients.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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